

REMARKS***Status of the Claims***

Claims 17, 21-24, 26, 28, 29, 31, 33, 38, and 42 are in the application.

Claims 17, 21-24, 26, 28, 29, 31, 33, 38, and 42 have been rejected.

Claims 17 is hereby amended to recite “consisting of” instead of “consisting essentially of.” No new matter has been added.

Upon entry of this amendment, claims 17, 21-24, 26, 28, 29, 31, 33, 38, and 42 will be pending.

Arguments***Rejection under 35 USC §103***

Claims 17, 21, 24, 26, 28, 29, 31, 33, 38, and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alila et al. in view of Draghia-Akli, Fewell et al, Goncalves (Cardiovascular Res., 45: 294-302, 2000), Nicosia et al. (American J. of Pathology, 145(5): 1023-1029, 1994) and Isner.

MPEP § 2143 provides that obviousness requires some suggestion or motivation in the reference themselves, or in the general knowledge of a skilled artisan, to modify the reference or to combine reference teachings to yield a reasonable expectation of success. It is respectfully submitted that the cited references, either alone or in combination, fail to render the claimed invention obvious. The claimed invention as amended relates to a promoter that consists of SEQ ID NO:3. Neither Alila, Draghia-Akli, nor any of the other cited references, alone or in combination, teach the claimed invention.

The Applicants submit that SEQ ID NO:3 is comprised of a 323 bp sequence and it is clear that Draghia-Akli does not teach SEQ ID NO:3, but rather discloses only a sequence identified and described as a 360 bp SacI/BamHI fragment of a SPc5-12 synthetic promoter. The

prior art fails to suggest what fragment or variant of the 360bp promoter taught in Draghia-Akli would function as a promoter, especially a fragment with the beneficial properties of the claimed promoter SEQ ID NO:3. Furthermore, none of Fewell, Goncalves, Nicosia, nor Isner are cited for any teaching related to muscle-specific promoters and do not disclose SEQ ID NO:3.

The arguments by the Patent Office in the outstanding action are improperly based on a combination of the Draghia-Akli reference – the 360 bp fragment – and the fact that the claimed invention functions as a promoter and is also referred to as a Sp5-12 promoter. The mere fact that a reference discloses a functional DNA sequence that acts as a promoter (such as an Sp5-12 promoter); that disclosure does not render obvious all future DNA sequences that act as a promoter in the same manner. The Applicants submit that the claimed promoter Sp5-12 (instant SEQ ID NO.:3) does have the Sp5 and Sp12 transcription factors bind thereto, similar to the Sp5-12 promoter discussed in Draghia-Akli reference. However, nowhere in that reference, or in the secondary references, is there any teaching or suggestion of what subset (fragment) can function as a promoter. As mentioned above, there are significant differences between the two sequences (over 10% truncation).

Moreover, in an effort to move this application to allowance, the Applicants have amended claim 17 to recite “consisting” and, therefore, it is even clearer that the cited references, alone or in combination, fail to render the claimed invention obvious.

Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. 103(a) are respectfully requested.

Claims 22-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alila et al. (cited above) in view of Draghia-Akli (cited previously), Fewell et al (cited previously), Goncalves (Cardiovascular Res., 45: 294-302, 2000, Nicosia et al. (American J. of Pathology, 145(5): 1023-1029, 1994) and Isner (cited previously) as applied to claims 17, 21, 24, 26, 28, 29, 31, 33, 38, 41, 42 above, and further in view of van Deutekom et al. (Mol. Med. Today, 214-220, May 1998).

Based on the argument provided, above, and considering that van Deutekom is not cited for and fails to disclose anything related to SEQ ID NO:3, Applicants submit that the cited references, alone or in combination, fail to render the claimed invention obvious.

Accordingly, claims 22 and 23 are not obvious over the cited art, and thus Applicants respectfully request the rejection be withdrawn.

In conclusion, the Applicants submit that all pending claims are in condition for allowance and request an early indication of the same. Should the Examiner have any questions that may be addressed through a teleconference, the Examiner is invited to contact the undersigned attorney.

The Commissioner is hereby authorized to charge any additional fees which may be required by this paper, or credit any overpayment to Account No. 50-4992.

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